



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/727,124 | 12/03/2003 | Francisco Arias | 2335-0108.10 | 4751 |
| 23980 7590 03/17/2009 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C 5 Palo Alto Square - 6th Floor 3000 El Camino Real PALO ALTO, CA 94306-2155 | | | | |
| EXAMINER VARGOT, MATTHEW D | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1791 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 03/17/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/727,124

Applicant(s)

ARIAS ET AL.

Examiner

Mathieu D. Vargot

Art Unit

1791

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-17 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9, 11-17 and 22-25 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

1.Applicant's election without traverse of Group I, claims 1-9, 11-17 and 22-25 in the reply filed on January 6, 2009 is acknowledged. The additional species has been dropped, leaving only product claim 26 as non-elected.

2.The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 8, 9, 11-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (see Figs. 6-8 and paragraphs 0144-0149; also see paragraph 0158).

Park et al discloses the basic claimed process for fabricating microneedles wherein a substrate material is provided, the substrate is coated with a photoresist, the photoresist is patterned photolithographically and the patterned photoresist is subsequently coated with a moldable material to make a mold —thereby forming a first microneedle structure, ie, instant claim 9 —which is then coated with a subsequent molding material to form an additional microneedle structure—ie, instant claim 11. Essentially, Park et al fails to explicitly teach that the patterned photoresist material would be separated from the substrate as set forth in instant claim 1. The applied reference continues to make molds and molds additional microstructures from the patterned photoresist, so it is clear that this resist is structurally sound enough to be employed in additional process steps. It is submitted that one of ordinary skill in the art would have found it obvious to have removed the patterned photoresist from the

substrate to facilitate additional processing on the photoresist. Note that the patterned photoresist, whether used as a mold or as a first generation microneedle structure, would constitute the instant microneedle structure. Park et al also lacks the aspects of using first and second resists, the exact aspect ratios of the microneedles and allowing moldable material to harden using a soft lithography procedure as set forth in instant claims 9 and 11. It is submitted that these aspects are all well known in the art and would have been obvious expedients in the process of Park et al to facilitate the formation of the microstructure and dependent on the exact structure desired. Note that Park et al applies moldable material and allows it to harden and such would certainly render obvious a similar step undertaken as "soft lithography". Grinding or polishing to open ends of tubes is well known and such would have been obvious in Park et al to form open channels in the microneedles. Also, it is well known to harden tips of microneedles by adding reinforcement and such would have been an obvious feature in Park et al to facilitate the insertion of the microneedles into the skin.

3. Claims 6 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of Smith (see 49 and 50 in Fig. 3).

Park et al discloses the basic claimed method as set forth in paragraph 2, *supra*, lacking essentially the aspect of etching around the base of the microneedle to create a break-away portion. Smith teaches that such is quite well known in the medical art when desiring to deliver medication using a needle—the ampoule has such a structure so that it can be easily broken. Since the aim of Park et al (see paragraph 0158) is to provide medication to the body by inserting the microneedles therein, it would have

been obvious to provide such an etched surface to facilitate the breakage of the microneedles in the body while the base is withdrawn.

4. Claims 4, 14 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of Prausnitz et al -211 (see passage bridging columns 21 and 22; see col. 8, lines 45+ and col. 16, lines 46-49).

Park et al discloses the basic claimed method as set forth in paragraph 2, supra, the primary reference failing to teach using a sacrificial between the substrate and the photoresist (instant claim 4) and applying a metal to the microneedle structure. As set forth in previous actions, Prausnitz et al -211 teaches a sacrificial layer (col. 21, line 56) and such is quite conventional in the art and an obvious feature in the method of Park et al. Prausnitz et al -211 also discloses making microneedles conductive by metal application and also that sensors would be incorporated into the microneedles. It would have been obvious to have modified the method of Park et al as taught by Prausnitz et al -211 to form a microneedle structure with an electrical—ie, sensor-- functionality.

5. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

In view of new grounds of rejection, applicant's comments directed to Prausnitz et al -211 as the primary reference are now moot. Suffice it to say, Park et al is a much better primary reference against the claims than Prausnitz et al -211, although the latter is applicable against certain dependent claims. What is lacking in Prausnitz et al -211—the use of the photoresist as a microneedle structure and the use thereof to make other molds and microneedle structures—is clearly taught in Park et al.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mathieu D. Vargot whose telephone number is 571 272-1211. The examiner can normally be reached on Mon-Fri from 9 to 6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson, can be reached on 571 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Vargot
March 15, 2009

/Mathieu D. Vargot/
Primary Examiner, Art Unit 1791